IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Attorney Docket No. 011738.00046

In re U.S. Patent Application of Hartlaub, et al.	)	
Application No. 10/002,669	)	Group Art Unit: 3686
Filed: October 31, 2001	)	Examiner: Najarian, Lena
For: Patient Scheduling Techniques For An Implantable Medical Device	)	Confirmation No. 5026

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Box Appeal Briefs - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Applicants respectfully request review of the final rejections in the above-identified application. No amendments are being filed with this request. The review is requested for the reasons stated in the below remarks. If any fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 19-0733, accordingly.

Remarks

Having received and reviewed the Office Action (10/10/08) and Advisory Action (12/23/08), and since the claims have been twice rejected, Applicant files this pre-appeal brief in accordance with 37 CFR 41.31(a), and respectfully submits that the standing rejections are based on one or more clear errors, and that the appeal process can be avoided through a pre-appeal brief review as set forth in the Official Gazette notice of July 12, 2005.

The specific errors relied upon in this Request for Review include the following:

- The Lebel reference (U.S. Publ. No. US 2002/0016568 A1) and the Pilarczyk reference (U.S. Patent No. 4,766,542) fail to disclose the subject matter of the rejected claims 12-15, 17-26, 39 and 44.

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- The Lebel reference, the Pilarczyk reference and the Mayer reference (U.S. Publication No. US 2002/0010597 A1) fail to disclose the subject matter of the rejected claims 40-41 and 45-46.
- The Lebel reference, the Pilarczyk reference and the Akers reference (U.S. Patent No. 6,112,182) fail to disclose the subject matter of the rejected claim 16.
- The Lebel reference, the Pilarczyk reference and the Cummings, Jr. reference (U.S. Patent No. 6,345,260) fail to disclose the subject matter of the rejected claims 42-43 and 47-48.

The References Fail to Disclose the Subject Matter of the Rejected Claims

Claims 12-15, 17-26, 39 and 44 were rejected under 35 USC §103(a) as being unpatentable over Lebel, et al., U.S. Publication No. 2002/0016568 A1 ("Lebel"), in view of Pilarczyk U.S. Patent No. 4,766,542 ("Pilarczyk"). Claims 40-41 and 45-46 were rejected under 35 USC §103(a) as being unpatentable over Lebel in view of Pilarczyk and further in view of U.S. Publication No. 2002/0010597 to Mayer et al. ("Mayer"). Claim 16 was rejected under 35 USC §103(a) as being unpatentable over Lebel in view of Pilarczyk and further in view of U.S. Patent No. 6,112,182 to Akers et al. ("Akers"). Claims 42-43 and 47-48 were rejected under 35 USC §103(a) as being unpatentable over Lebel in view of Pilarczyk and further in view of U.S. Patent No. 6,345,261 to Cummings, Jr. et al. ("Cummings, Jr.").

Independent claim 12 substantively recites: An implantable drug delivery device for delivering at least one drug to a patient comprising in combination:

(a) at least one reservoir each containing at least one drug;

(b) a drug scheduling module for determining whether the drug should be replenished;

(c) an appointment scheduling module automatically initiated by the drug scheduling module and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device; and

(d) a telemetry module providing bi-directional communications with an external device for allowing the appointment scheduling module to schedule the appointment,

wherein the drug scheduling module receives data about the implantable drug delivery device, wherein the data is selected from the group consisting of drug usage information and drug management data.

Independent claim 21 substantively recites the following: An implantable drug delivery device having a patient scheduling feature, comprising:

(a) a housing;

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(b) a drug reservoir carried in the housing configured to contain a therapeutic substance;

(c) a flow control coupled to the drug reservoir for controlling the flow of the therapeutic substance from the drug reservoir through an infusion port;

(d) electronics coupled to the flow control and a power source;

(e) a telemetry module coupled to the electronics;

(f) memory coupled to the electronics, the memory containing pump scheduling criteria and other scheduling criteria;

(g) a monitoring module coupled to the memory and the electronics that monitors at least one pump operation variable; and,

(h) a scheduling module coupled to the memory and the electronics, the scheduling module configured to calculate at least one relationship among the pump scheduling criteria and monitored pump variables, the scheduling module configured to decide automatically and without scheduling input contemporaneously provided by the patient whether an appointment is required, and the scheduling module configured to activate the telemetry module to schedule an appointment, wherein the scheduling module is adapted to contact via the telemetry module at least one entity for the appointment scheduling automatically, and without scheduling input contemporaneously provided by the patient, wherein the at least one entity is selected from the group consisting of a pharmacy, a caregiver, a physician, and a hospital.

Referring to claim 12, the Office Action of 10/10/08 recognized that Lebel does not disclose "an appointment scheduling module automatically initiated by the drug scheduling module, and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device and allowing the appointment scheduling module to schedule the appointment." Referring to claim 21, the Office Action recognized that Lebel does not disclose "the scheduling module configured to decide automatically and without scheduling input contemporaneously provided by the patient whether an appointment is required and to contact at least one entity for the appointment scheduling automatically, and without scheduling input contemporaneously provided by the patient." The Office Action contended that Pilarczyk discloses such features in Col. 1, line 52 through Col. 2, line 34 and Col. 6, lines 15-55.

It is respectfully submitted that Pilarczyk does not teach these features and therefore does not remedy the deficiencies of Lebel. Rather, the cited sections of Pilarczyk describe "a computerized system for contacting patients whose prescriptions are due to be refilled." (Col. 1, lines 52-52) Pilarczyk does not disclose or suggest an appointment scheduling module as recited in independent claim 12, but is instead directed to "a system for contacting customers of a

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pharmacy automatically to remind them that their prescriptions need to be refilled...." *See* Abstract of Pilarczyk. *See also* Abstract of Pilarczyk: "The voice synthesizer then reminds the customer that the prescription is due to be refilled if the medication was taken as prescribed." [Emphasis added] There is no automatic scheduling of an appointment taught in Pilarczyk and the reminder is based only on an assumption that the medication was taken at the rate it was prescribed. Nowhere in Pilarczyk is the word "appointment" mentioned, and nowhere does Pilarczyk disclose an "appointment scheduling module to schedule the appointment" as claimed in independent claim 12 or a "scheduling module configured to activate the telemetry module to schedule an appointment" as claimed in independent claim 21.

The proposed combination of Lebel and Pilarczyk does not result in a scheduling module as claimed in claims 12 and 21 because there is a conceptual link missing between providing a module that automatically schedules an appointment, as claimed, and the disclosures of the two cited documents: a drug device with an audible alarm (Lebel) and a telephonic reminder system (Pilarczyk). Moreover, there would have been no reason for one of skill in the art to be motivated to provide an automatic scheduling module automatically initiated by a drug scheduling module, as recited in the instant claims, from the disclosures of Lebel and Pilarczyk. For instance, Lebel discloses a goal to "enhance user interface capabilities in ambulatory medical systems and in particular for implantable infusion pump systems." Lebel states a concern for greater user involvement and thus it would not have made sense to eliminate user interaction by employing automatic appointment scheduling.

Mayer does not remedy the deficiencies of Lebel and Pilarczyk. Mayer is directed to a set of software tools for a consumer to use for taking control of his or her own medical care. (*See* Abstract of Mayer). An appointment making tool is disclosed in paragraph 50 of Mayer: "This tool confirms, tracks and keeps appointments organized. For example, a patient needing an appointment for a physical." Mayer teaches appointment scheduling upon receiving a request from a ***patient*** for an appointment, as opposed to having a separate entity (i.e., a drug scheduling module) automatically initiating the request for an appointment. Although a pharmacist tool is disclosed in paragraph 39 of Mayer to give "an estimation of compliance and can prompt for refills to improve compliance," there is no further disclosure with respect to prompting for refills, such as how the pharmacist tool could actually provide a prompt. There would have been no

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reason for one of ordinary skill in the art to remove the patient from involvement with the appointment making tool as disclosed in paragraph 50 of Mayer and configure the pharmacist tool as disclosed in paragraph 39 of Mayer to initiate the separate appointment making tool sans patient involvement.

Akers is directed to a data processing system for use in managing healthcare and is unrelated to appointment scheduling, thus also does not remedy the deficiencies of the cited art.

Cummings, Jr. is directed to an appointment scheduling interface for booking appointments with professionals. (*See* Col. 1, lines 13-16 of Cummings, Jr.) Cummings, Jr. does not remedy the deficiencies of Lebel and Pilarczyk with respect to either claim 12 or claim 21. Cummings, Jr. discloses a "[c]all center, to which clients can call through conventional telephone lines. (Col. 6, lines 46-47) "While client 10b is on the line, call center 11 can log onto the Web from any Web browser. With proper security clearance and verification, server 15 permits access to online master schedule database 16, which contains and displays the appointment times and dates for all physicians on the system..." (Col. 8, lines 1-7) Appointment scheduling is therefore disclosed by Cummings, Jr. to be initiated by a ***client call*** to a call center.

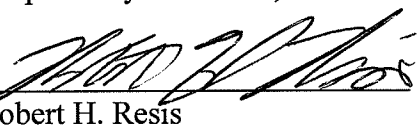
In sum, the pending independent claims are each patentable over the cited art. The pending dependent claims are patentable over the cited art for at least the same reasons as independent claims from which they depend and for the additional features recited therein. The Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. §103(a) rejections.

CONCLUSION

While Applicant believes the above points represent the clearest errors made by the Office, Applicant reserves the right to appeal on other bases and errors should the appeal of this case proceed after the Office's consideration of this paper. All issues having been addressed, Applicant respectfully submits that the instant application is in condition for allowance, and respectfully solicits prompt notification of the same.

Respectfully submitted,

Dated: January 12, 2009

By: 

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